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09/909,101	07/19/2001	Jonathan J. Langberg	MITRAL.ICPIDI	9876

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EXAMINER
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CHATTOPADHYAY, URM1

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/11/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/909,101

Applicant(s)

LANGBERG ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 23-25, 30-32, 34, 36-39, 44-49, 52-58, 62-65, 68-71, 73, 75, 76 and 81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5-22,26-29,33,35,40-43,50,51,59-61,66,67,72,74 and 77-80.

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 5/23/03 has been entered as Paper No. 10. The changes to the specification and claims have been approved by the examiner. New claims 23 -81 have been added. The indicated allowability of claims 1-6 over the prior art in the office action mailed 1/2/03 is withdrawn in view of the newly discovered reference(s) to Wilson et al. Rejections based on the newly cited reference(s) follow.

### ***Election/Restrictions***

2. Applicant's election of Species (1)(b), (2)(a), (3)(a) and (4)(c), claims 1-6, 23-25, 30-32, 34, 36-39, 44-49, 51-58, 62-65, 68-71, 73, 75, 76 and 81 in Paper No. 13 is acknowledged. The examiner agrees with applicant's inclusion of Subspecies (c) under Species 4 directed to the anchor being a barb for piercing the wall of the vessel.

3. In addition to those claims withdrawn from consideration by applicant, the examiner is also withdrawing claim 5 for the same reason applicant withdrew claim 50, claim 6 for being dependent on claim 5, and claim 51 for being dependent on withdrawn claim 50. Claims 1-81 are pending; claims 5-22, 26-29, 33, 35, 40-43, 50, 51, 59-61, 66, 67, 72, 74 and 77-80 have been withdrawn from consideration; claims 1-4, 23-25, 30-32, 34, 36-39, 44-49, 52-58, 62-65, 68-71, 73, 75, 76 and 81 are being considered for further examination on the merits. Claims 1 and 46 are generic.

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### *Drawings*

4. The drawings are objected to because in light of the amendment to the specification, which designates "tissue contacting surface" as element "115", Figure 5 must now be corrected by changing "114" to --115--. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

5. Claim 70 is objected to because of the following informalities: it appears that "10 mm" on line 2 should be changed to --10 mm<sup>2</sup>--. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 23-25, 30-32, 34, 36, 37, 39, 44-48, 52-58, 62-65, 69-71, 75 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (USPN 6,569,198 as cited in PTO-892 mailed 9/9/03).

Wilson et al. discloses a method of performing transluminal mitral annuloplasty with all the elements of claims 1 and 46. See column 6, lines 8-10 and column 7, lines 26-28 for

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providing a catheter, having either the prosthesis (12) of Figure 2 or the prosthesis (100) of Figure 6 thereon. See column 3, lines 35-46 for inserting the catheter into the venous system and transluminally advancing the prosthesis into the coronary sinus. See column 3, lines 58-61 and column 4, lines 16-19 for rotating a component (control wires) of the prosthesis with respect to a second component of the prosthesis. See Figures 5 and 8 and column 7, line 28 for releasing the prosthesis from the catheter, such that the prosthesis exerts a force on the wall of the coronary sinus.

Claims 2, 3, 47 and 48, see column 3, lines 44-46 and column 6, lines 2-4.

Claim 23, see column 7, lines 13-21 for the rotating a component step causing the prosthesis to bend into an arcuate configuration.

Claims 24, 25, 57, 58, 62, 63 and 75, see column 7, lines 13-21 for locking the prosthesis in the arcuate configuration by engaging a first threaded surface (126) with a second threaded surface (threaded section of control wire 122).

Claim 30, see Figures 5 and 8 for deploying the prosthesis in the coronary sinus.

Claim 31, see column 7, line 28 for removing the catheter from the venous system.

Claims 32, 34, 39, 71, 73 and 76, see column 6, lines 34-38 for monitoring hemodynamic function during the rotating step using transesophageal echo cardiography.

Claim 36, see column 7, lines 16-21 the rotating step resulting in axially moving a forming element (122) to bend the prosthesis (100).

Claim 37, see column 7, line 28 for using a catheter.

Claims 44 and 45, see column 4, lines 16-22 for tightening the prosthesis, by rotation of the control wire, to achieve at reduction in regurgitation.

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Claims 52 and 53, see column 5, lines 61-65, column 6, lines 31-33 and lines 38-42, and column 7, lines 15-21 the rotating step reversibly changing the shape of the prosthesis from an implantation configuration to a remodeling configuration.

Claims 54 and 55, see Figure 8 and column 7, lines 16-21 for prosthesis defining an arc.

With respect to claims 56 and 70, see Figure 8. Because the prosthesis is implanted into the coronary sinus in order to perform mitral valve annuloplasty, it is inherent that the prosthesis dimensions and arc will meet the required range.

Claim 64, see column 7, lines 42-44 for a coating on the prosthesis.

Claim 65, see Figure 4b for deploying an anchor (72) for retaining the prosthesis at the deployment site within a vessel.

Claim 69, see columns 4-5, lines 66-2 for total axial length being less than 10 cm.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 38 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. in view of Rhee et al. (USPN 6,019,739).

Wilson et al. discloses a method of performing transluminal mitral annuloplasty with all the elements of claims 1 and 46, but is silent to the additional limitation of first measuring the coronary sinus and then selecting an appropriately sized prosthesis prior to the inserting step, as

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required by claims 4, 38 and 49. Examiner contends that measuring a body part for selecting an appropriately sized prosthesis is old and well known in the art. For example, Rhee et al. teaches measuring the size of a heart valve annulus during annuloplasty surgery in order to select a properly sized annuloplasty ring. See column 1, lines 5-11. Therefore, it would have been obvious to one of ordinary skill in the art to measure the coronary sinus and then select an appropriately size prosthesis prior to the inserting step in order for the prosthesis to function properly, without being displaced for being too small or damaging tissue for being too big for examples, once it is inserted into the coronary sinus.

10. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. in view of Solem et al. (USPN 6,210,432 as cited in applicant's IDS).

Wilson et al. discloses a method of performing transluminal mitral annuloplasty with all the elements of claim 46, but is silent to the deploying an anchor step comprising deploying at least one barb for piercing the wall of the vessel, as required by claim 68. Solem et al. teaches an anchor comprising at least one barb for piercing the wall of the vessel in order to retain the device within the vessel that the desired location. See column 4, lines 23-25. While the spring coil mechanism of Wilson et al. and the barbs of Solem et al. serve the same purpose of anchoring, the barbs are much more simple than the coil mechanism. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention, therefore, to look to the teachings of Solem et al. and replace the coil mechanism of Wilson et al. with the barbs of Solem et al. in order to reduce the complexity of the device.



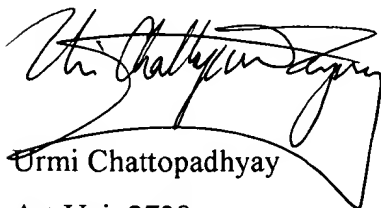
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11. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. in view of Kadhiresan (USPN 5,935,081).

Wilson et al. discloses a method of performing transluminal mitral annuloplasty with all the elements of claim 46, but is silent to the additional limitation of determining an ongoing drug therapy taking into account post implantation residual regurgitation, as required by claim 81. Kadhiresan teaches monitoring the heart beat of a patient suffering from cardiac abnormalities, and in the presence of a third heart sound, which indicates mitral regurgitation, optimizing a drug therapy for treatment thereof. See column 4, lines 8-46. Therefore, it would have been obvious to one of ordinary skill in the art to look to the teachings of Kadhiresan to add to the method of Solem et al. and Griffith et al. the step of determining an optimized ongoing drug therapy taking into account post implantation residual regurgitation.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella  
Primary Examiner